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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,950

05/19/2006

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P28510

6546

7055 7590 06/30/2009  
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EXAMINER

ZALASKY, KATHERINE M

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

06/30/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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### DETAILED ACTION

**Claims 1 and 13-19**, as amended 12 May 2009, are currently pending. **Claims 2-12** are cancelled.

#### *Claim Rejections - 35 USC § 102*

1. **Claims 1 and 13** are rejected under 35 U.S.C. 102(b) as being anticipated by Fukasawa et al. (EP 0306613).

Regarding **claim 1**, Fukasawa et al. discloses a hollow fiber membrane type fluid treatment device (pg 3, L19-22) comprising:

- at least a body portion of tubular housing (15) containing a hollow fiber membrane bundle (17)
- a housing head portion (29) which is connected with one end of the housing body portion and has a resin layer (19) where the hollow fiber membrane bundle is fixed by using a resin composition (pg 6/L16-25) and a connection port (27) which serves as a treatment liquid inlet
- a housing head portion (30) which is connected with the other end of the housing body portion and has a resin layer (18) where the hollow fiber membrane bundle is fixed by using a resin composition (pg 6/L16-25) and a connection port which serves as a treatment liquid outlet (28)
- header caps (20, 21) attached to the housing head portions and having respective treatment target liquid connection ports (23, 25)
- an inner surface of a body portion of the tubular housing at the side of a treatment liquid inlet comprises a body straight portion (Figures 3-4,

straight portions on the inner surface, near to ports 27 & 28) and an end tapered portion which increases in diameter toward the end face of the housing body portion (Figure 3)

- the hollow fiber membranes are arranged so that a distance between the hollow fiber membranes is gradually increased toward the end face on the treatment liquid inlet side along a taper of a tapered portion of the inner surface of the housing body portion (Figure 3 & pg 5/L22-33)

Regarding **claim 13**, Fukasawa et al. discloses all of the claim limitations as set forth above. Additionally, the reference discloses the device wherein the tapered portion comprises:

- a first tapered portion located on the body portion side (Figure 3, tapered portions by passages 29 & 30)
- a second tapered portion located on the treatment liquid inlet side (Figure 3, tapered portions by ports, 27 & 28)
- the angle of the first taper angle is smaller than the angle of the second taper angle (Figure 3, pg 4/L57 – pg 5/L2)

Regarding limitations recited in **claim 1** which are directed to a manner of operating disclosed apparatus (“wherein a liquid to be treated flows within the hollow fiber membranes and a treatment liquid flows outside of the hollow fiber membranes”), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held

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that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

***Claim Rejections - 35 USC § 103***

2. **Claims 14-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukasawa et al. (EP 0306613), as applied to **claim 1** above.

Regarding **claim 14**, Fukasawa et al. discloses all of the claim limitations as set forth above, but does not explicitly disclose the device wherein an angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than  $0^\circ$  and smaller than an angle defined by  $\tan^{-1} \{(1/2) \cdot (d1-d4)/L4\}$ . As the packing density and thus the efficiency of treatment fluid exchange are variables that can be modified, among others, by adjusting said angle, the precise angle would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made (see pg 5, L25-28). As such, without showing unexpected results, the claimed angle cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the angle in the apparatus of modified Fukasawa to obtain the desired packing density and efficiency (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

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Regarding **claim 15**, Fukasawa et al. discloses all of the claim limitations as set forth above, but does not explicitly disclose the device wherein an angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than  $0.58^\circ$  and smaller than an angle defined by  $\tan^{-1} \{(1/2) \cdot (d1-d4)/L4\}$ . As the packing density and thus the efficiency of treatment fluid exchange are variables that can be modified, among others, by adjusting said angle, the precise angle would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made (see pg 5, L25-28). As such, without showing unexpected results, the claimed angle cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the angle in the apparatus of modified Fukasawa to obtain the desired packing density and efficiency (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding **claim 16**, Fukasawa et al. discloses all of the claim limitations as set forth above. While the reference does not explicitly disclose the ratio of the length of the body straight portion to the total length of the end tapered portion being between 0.7 to 20 and the ratio of the inner diameter of the end tapered portion on the end face side to the inner diameter of the body straight portion being more than 1 and not more than 3, since the instant specification is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the lengths of the tapered and

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straight body portions as well as the diameters, since such a modification would have involved a mere change in the size (or dimension) of a component. A change in size (or dimension) is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device, and the device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device, *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Regarding **claim 17**, modified Fukasawa discloses all of the claim limitations as set forth above. Regarding limitations recited in **claim 17** which are directed to a manner of operating disclosed device (e.g. “a urea clearance of 191 to 200 ml/min”), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

3. **Claims 18-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukasawa et al. (EP 0306613), as applied to **claim 1** above, and further in view of Kanno et al. (US 4,201,673).

Regarding **claims 18-19**, Fukasawa et al. discloses all of the claim limitations as set forth above. The reference does not explicitly disclose the device comprising baffle plates provided at positions corresponding to the treatment liquid inlet and the treatment liquid outlet of the tubular housing and interspatially from the inner circumference of the tubular housing over the entire inner circumference at a curvature almost along the inner circumference. Further, the reference does not disclose the device wherein the baffle plate gradually increases in diameter toward the end face of the housing.

Kanno et al. discloses a dialyzer with hollow fiber membranes (abstract) which contains a baffle plate (annular rib 15) which increases in diameter toward the end of the housing (see Figures 2 &3). Kanno et al. teaches that a baffle plate may help avoid channeling and may improve efficiency by allowing dialysate to flow over the outermost hollow fibers (C1/L45-60).

Fukasawa et al. and Kanno et al. are analogous because both references are directed to hollow fiber membrane modules.

It would have been obvious to one having ordinary skill in the art at the time of the invention to add a baffle plate to the module of Fukasawa et al, as taught by Kanno et al., since doing so may help avoid channeling, thereby improving the efficiency of the device.

### ***Response to Arguments***

4. Applicant's arguments filed 12 May 2009 have been fully considered but they are not persuasive.



In response to Applicant's argument that Fukasawa does not teach a body straight portion, the Applicant is directed to Figure 3 and 4, where the body is straight near ports 27 & 28. There are no further limitations in the claims as to where the straight portion of the body is located (i.e., center or opposing ends). Even if such a limitation were added to the claims however, it would have been obvious to one of ordinary skill in the art to include a straight portion in the very center of the body since doing so is nothing more than a design choice which would extend the length of the body.

In response to Applicant's argument that Fukasawa does not teach the specified liquids flowing through and around the hollow fiber membranes, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In response to Applicant's argument that the device of Kanno results in the hollow fibers being more densely packed in the head portions than in the body portion, it is noted that Kanno is used to teach a circumferential baffle plate which helps prevent channeling.

In response to Applicant's argument that Kanno and Fukasawa are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for

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rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both references are directed to hollow fiber membrane modules with ports on either end cap and ports on the sides of the body. Further, both references, like the instant application, are directed to the treatment of blood. Finally, all references have hollow fiber membranes which flare out in the header portions. Therefore, this argument is not persuasive.

### ***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE ZALASKY whose telephone number is

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(571) 270-7064. The examiner can normally be reached on Monday-Thursday, 7:30am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/  
Primary Examiner, Art Unit 1797

/KZ/  
24 June 2009